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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,002	12/20/1999	PAUL NEGULESCU	AURO1130-2	3109

7590 10/24/2002  
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 10/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/468,002

Applicant(s)

NEGULESCU ET AL.

Examiner

Robert Landsman

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1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 63,66-71,74,75,78-81,84-90,93,94,97-102 and 105-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63,66-71,74,75,78-81,84-90,93,94,97-102 and 105-138 is/are rejected.
- 7) ☒ Claim(s) 139-145 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**4. Claim Rejections - 35 USC § 112, first paragraph – enablement**

A. Claims 63, 66-71, 74, 75, 78-81, 84-90, 93, 94, 97-102 and 105-138 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on pages 4-6 of the Office Action dated 8/21/02 because the specification, while being enabling for a method of identifying a GPCR for a given ligand, identifying a ligand for a given GPCR, or identifying modulators of GPCR signal transduction (Example 6, page 42 and Example 8, pages 43-44) using only the stable cell lines produced in Example 4 of the specification, does not reasonably provide enablement for a method of identifying GPCRs for a given ligand, identifying a ligand for a given GPCR, or identifying modulators of GPCR signal transduction in any stable cell line other than that of Example 4 in the specification.

Applicants argue that the Declaration by Dr. Mel Simon under 37 CFR 1.132 does not indicate that only the cells of Example 4 can be used to practice the methods and that these cell lines can be functionally selected using a signal transduction detection system described in the present application. These arguments have been considered, but are not deemed persuasive. The issue, respectfully, remains that Applicants have argued that the present invention would not have been obvious to one of ordinary skill in the art since these cell lines were difficult to produce. While this may have made the present invention not obvious under 35 USC 103, it does raise the question of enablement since Applicants were only able to produce one stable cell line (i.e. using only one specific vector, promoter and host cell). Since a promiscuous G protein 100% identical to SEQ ID NO:2 was known in the prior art at the time of the invention, it would have been obvious for the artisan to have transfected a cell to express this protein in order to perform binding studies, since this is common practice in the art (see page 10 of the Office Action dated 11/23/01). The fact that Applicants argue that this procedure is not obvious brings to light the question of why this is not obvious. Applicants argue that the specific requirements need to be followed, such as the use of an inducible promoter, make this invention not obvious. Applicants argue that the stable cell is one that is determined by functional analysis with a signal transduction detection system. However, Applicants have only been able to identify one such cell line. Due to the difficulty of producing these cell lines, Applicants have not enabled the present invention for any other cell lines than the one disclosed in the present invention, regardless of the techniques used to identify these cell lines.

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*4. Claim Rejections - 35 USC § 112, first paragraph – enablement*

A. Claims 63, 66-71, 74, 75, 78-81, 84-90, 93, 94, 97-102 and 105-138 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons already of record on pages 4-6 of the Office Action dated 8/21/02 because the specification, while being enabling for a method of identifying a GPCR for a given ligand, identifying a ligand for a given GPCR, or identifying modulators of GPCR signal transduction (Example 6, page 42 and Example 8, pages 43-44) using only the stable cell lines produced in Example 4 of the specification, does not reasonably provide enablement for a method of identifying GPCRs for a given ligand, identifying a ligand for a given GPCR, or identifying modulators of GPCR signal transduction in any stable cell line other than that of Example 4 in the specification.

Applicants argue that the Declaration by Dr. Mel Simon under 37 CFR 1.132 does not indicate that only the cells of Example 4 can be used to practice the methods and that these cell lines can be functionally selected using a signal transduction detection system described in the present application. These arguments have been considered, but are not deemed persuasive. The issue, respectfully, remains that Applicants have argued that the present invention would not have been obvious to one of ordinary skill in the art since these cell lines were difficult to produce. While this may have made the present invention not obvious under 35 USC 103, it does raise the question of enablement since Applicants were only able to produce one stable cell line (i.e. using only one specific vector, promoter and host cell). Since a promiscuous G protein 100% identical to SEQ ID NO:2 was known in the prior art at the time of the invention, it would have been obvious for the artisan to have transfected a cell to express this protein in order to perform binding studies, since this is common practice in the art (see page 10 of the Office Action dated 11/23/01). The fact that Applicants argue that this procedure is not obvious brings to light the question of why this is not obvious. Applicants argue that the specific requirements need to be followed, such as the use of an inducible promoter, make this invention not obvious. Applicants argue that the stable cell is one that is determined by functional analysis with a signal transduction detection system. However, Applicants have only been able to identify one such cell line. Due to the difficulty of producing these cell lines, Applicants have not enabled the present invention for any other cell lines than the one disclosed in the present invention, regardless of the techniques used to identify these cell lines.

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B. The deposit of the biological material is considered necessary for the enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If a deposit (the stable COS-7 cell line) is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration containing the following:

1. the current address of the ATCC.
2. a declaration, or statement over attorney's signature stating that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent (see MPEP Chapter 2410.01 and 37 C.F.R. § 1.808).

***5. Claim Rejections - 35 USC § 112, second paragraph***

A. Claims 63, 66-71, 74, 75, 78-81, 84-90, 93, 94, 97-102 and 105-138 remain rejected under 35 U.S.C. 112, second paragraph, for the reasons already of record on page 8 of the Office Action dated 8/21/02, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. Applicants argue that the Declaration by Dr. Mel Simon under 37 CFR 1.132 does not indicate that only the cells of Example 4 can be used to practice the methods and that these cell lines can be functionally selected using a signal transduction detection system described in the present application. These arguments have been considered, but are not deemed persuasive.

As argued in the above rejection under 35 USC 112, first paragraph, the issue is that Applicants were only able to produce one stable cell line (i.e. using only one specific vector, promoter and host cell). Applicants argue that specific requirements need to be followed, such as the use of an inducible promoter. Applicants argue that the stable cell is one that is determined by functional analysis with a signal transduction detection system. However, Applicants have only been able to identify one such cell line.

B. All other rejections under 35 USC 112, second paragraph, on pages 8-10 of the Office Action dated 8/21/02 (paragraphs F-L), have been withdrawn in view of Applicants' amendments to the claims

***6. Conclusion***

A. Claims 139-145 would be allowable if rewritten in independent format and include all limitations of the claims from which they depend.

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*Advisory information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
October 28, 2002

